

Remarks

This Paper is responsive to the Office Action mailed December 24, 2003 (Paper No. 9). Entry of this Paper and reconsideration of the subject application in view thereof are respectfully requested.

Claims

Claims 1-23 are pending. Claims 1-23 stand rejected. In the present response, claim 9 has been cancelled without prejudice and claims 1, 5 and 23 have been amended. Support for amendments is inherent or as indicated below. No new matter is added.

Rejections under 35 U.S.C. §112, Second Paragraph

Claim 5 stands rejected under 35 U.S.C. §112(2) as being allegedly indefinite in recitation of a cosmetic agent selected from the group consisting of anti-acne agents.

Claim 5 has been amended to recite a “cosmetic agent comprised of at least one anti-acne agent.” Withdrawal of rejection is respectfully requested.

Claim 23 stands rejected under 35 U.S.C. §112(2) as being vague. In particular, the Examiner alleged that the claim is confusing and it is not clear what is rinsed from the skin.

Applicants have amended claim 23 to more clearly recite that the skin is rinsed, as opposed to “rinsing the delivery discs from the skin.” Support can be found in the specification in page 4, paragraph 12. Claim 23 as amended is sufficiently definite for purposes of 35 U.S.C. §112, second paragraph. Withdrawal of rejection is respectfully requested.

Rejections under 35 U.S.C. §102(b)

Claims 1-4, 6-8 20 and 22 stand rejected under 35 U.S.C. §102(b) as being anticipated by Lorenz et al. (U.S. Patent No. 5,420,197). In particular, the Examiner alleged that Lorenz discloses a composition that comprises a polyvinylpyrrolidone, wetting, dispersing agents or surfactants, glycerin and polyethylene glycol, biologically active agents or cosmetic agents and fragrances, dyes, pigments and fillers. In addition, the Examiner asserted that Lorenz teaches application of the composition to wet skin and would inherently clean the skin.

Applicants traverse this rejection and respectfully assert that the pending claims are not anticipated by Lorenz et al. The Lorenz invention is a wet gel which is pre-dissolved and does not dissolve when applied to mucosa. The composition taught by Lorenz focuses on formulations that include water and would not dissolve when applied to mucosa.

In contrast, claims 1-4, 6-8, 20 and 22, as amended, are directed to a dry uniform mixture that dissolves when applied to wet tissue, or to dry tissue with a few drops of water. The product is dry and dissolves when applied; it is not a wet gel such as that of Lorenz. As such, Lorenz et al. does not anticipate claims 1-4, 6-8, 20 or 22. Support can be found inherently in the specification in Examples 1-8 (pages 9-13), all of which refer to the final step of drying the product in an oven until the film is uniform and non-tacky. Thus, no new matter is added. Withdrawal of rejection is respectfully requested.

Claims 1, 3 and 21 stand rejected under 35 U.S.C. §102(b) as being anticipated by Leonard et al. (U.S. Patent No. 4,820,525). The Examiner alleged that Leonard discloses a transdermal delivery system that comprises a polyethylene polymer and estradiol in the form of disk. The Examiner further alleged that transmucosal delivery system in a disk form implies application of a composition comprising estradiol and polyethylene polymer to the mucosa.

Applicants disagree. A claim is anticipated by a reference only if each and every element of the claim is found, either expressly or inherently, in that reference. *MPEP 2131*. Moreover, the identical invention must be shown in **as complete detail as is contained in the claim**. *Id.* Abiding by these standards, Leonard et al. clearly does not anticipate the invention as claimed in claims 1-23.

Because Leonard et al. teaches the use of a non-porous patch (column 3, lines 19-35) containing polyethylene foamed material and having an “occlusive backing,” (see column 4, lines 60-65) the composition would inherently not dissolve when applied to mucosa. Applicants assert that one of ordinary skill in the art would know that a composition comprising polyethylene foam would not dissolve when applied to mucosa; the polyethylene foam material simply prevents such a dissolution on skin. In contrast, the present invention requires that the composition dissolve when applied to wetted skin. Thus, Leonard et al. does not anticipate claims 1, 3 or 21. Withdrawal of rejection is respectfully requested.

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Rejections under 35 U.S.C. §103(a)

Claims 9-19 stand rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Lorenz et al. (U.S. Patent No. 5,420,197). While conceding that Lorenz et al. does not disclose the amounts of additives in the composition as recited in the instant claims, the Examiner alleges that it would have been obvious to one of ordinary skill in the art at the time the invention was made to prepare a composition where the amounts of the additives are optimized to yield a delivery composition that would be expected to deliver active substances at the site of delivery and at a desired rate of delivery.

Applicants respectfully traverse this rejection and assert that claims 9-19 are patentable over Lorenz et al. First, as discussed above, Lorenz does not teach or suggest, either expressly or inherently, a dry composition that dissolves when applied to wetted skin. To the contrary, Lorenz teaches formulations that include water. As the present invention teaches and requires a dry uniform mixture which dissolves on wetted skin tissue, one of ordinary skill in the art would not, using Lorenz et al., arrive at the present invention absent undue experimentation.

Withdrawal of rejection is respectfully requested.

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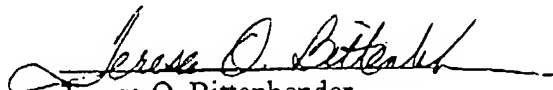
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Closing Remarks

Applicants thank the Examiner for the Office Action and believe this response to be a full and complete response to such Office Action. Accordingly, favorable reconsideration in view of this response and allowance of the pending claims are earnestly solicited.

Respectfully submitted,



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